Fluid restriction in patients with heart failure: a systematic review

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ABSTRACT

Background Fluid restriction is a commonly prescribed non-pharmacological intervention in the management of heart failure (HF). However, data on its efficacy and safety are scarce. Recent randomised clinical trial (RCT) data prompt reassessment of the available evidence.

Methods CINAHL, EMBASE, PubMed and the Cochrane Library were searched up to 1 May 2025. RCTs were included if adults with HF were randomised to fluid restriction in comparison to a liberal or unrestricted intake, less strict restriction or usual care. Outcomes of interest were mortality, HF hospitalisation, quality of life (QoL), thirst distress, New York Heart Association (NYHA) class and N-terminal pro-Brain Natriuretic Peptide (CRD42022292319). No meta-analysis was performed due to high heterogeneity of the included trials.

Results In total, four RCTs were included, comprising 682 randomised inpatient, recently discharged and stable outpatient patients (ranging from 46 to 504 patients per trial). Only one study had a low risk of bias. None of the four trials found a significant difference in mortality or HF hospitalisations. For QoL, the results are contradictory, but overall, there is no clear benefit for fluid restriction, but it resulted in more thirst distress. No significant differences in NYHA class or (NT-pro)BNP were observed.

Conclusion Studies on fluid restriction in patients with HF are scarce, and most of the available studies are at high risk of bias. Although power is lacking, there is no evidence indicating that fluid restriction affects mortality or HF hospitalisations, but there is a signal of harm in terms of thirst distress. Taken together, the current evidence does not support the routine use of fluid restriction in patients with HF.

INTRODUCTION

Heart failure (HF) is a growing burden affecting millions of people worldwide.[1] Although pharmacotherapy reduces mortality and HF hospitalisations and improves quality of life (QoL), patients with HF still experience a high symptom burden and remain at high risk of adverse events.[2 3] In order to improve outcomes and QoL, non-pharmacological therapy may also be of benefit for patients with HF.[4]

In this context, fluid restriction has been a common clinical intervention for patients with HF, with the assumption that it may reduce or prevent episodes of congestion and subsequent hospitalisation.[5–9] But clear evidence of such a positive effect is lacking, and there is limited data that fluid restriction may even adversely impact patients, leading to increased sense of thirst, decreased caloric intake and decreased QoL.[10 11]

The lack of sufficient evidence regarding the efficacy of fluid restriction is explicitly stated in both the latest 2021 European Society of Cardiology (ESC) Guidelines for the diagnosis and treatment of acute and chronic HF and the 2022 American College of Cardiology/American Heart Association/HFSA guideline for the Management of HF.[3 12] In this context, these guidelines only provide a general comment to avoid large volumes of fluid intake, without specifying an upper limit, and suggest that fluid restriction may only be considered in severe HF or those with hyponatraemia. In contrast, in 2024, the ESC Heart Failure Association recommended a normal intake ranging between 1500 and 2500 mL per day for patients with HF and do not advocate fluid restriction.[13] This ambiguity between these guiding documents clearly demonstrates the paucity of robust data. This led us to perform a systematic review to reassess the available evidence on fluid restriction in HF on clinical outcomes.

METHODS

This systematic review was conducted in accordance with the Cochrane Handbook for Systematic Reviews of Interventions and the Preferred Reporting Items for Systematic reviews and Meta-Analyses statement and was registered in PROSPERO, the International Prospective Register of Systematic Reviews (study identifier: CRD42022292319).[14 15] Patients were not involved in the design and conduct of this systematic review. A meta-analysis was ultimately considered inappropriate due to the substantial clinical and methodological heterogeneity of the included studies, results are reported descriptively.

Inclusion criteria and outcomes

Randomised controlled trials (RCTs), both parallel and cross-over studies, in any language were included if the effect of a fluid restriction was investigated in comparison to a liberal or unrestricted fluid intake, less strict fluid restriction or usual care in adult inpatient and outpatient with HF without limitations in aetiology, left ventricular ejection fraction or New York Heart Association (NYHA) class.

This systematic review aims to examine all available peer-reviewed evidence on the effects of fluid restriction in patients with HF. Studies that performed multiple interventions simultaneously (eg, fluid restriction combining with sodium restriction or diuretics) as well as behavioural or educational studies (investigating patients' adherence rather than the effects of the dietary interventions) were excluded from this review.

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By excluding studies in which other interventions were initiated simultaneously, potential interference was reduced, enabling a more accurate evaluation of the effect.

Primary outcomes were mortality and HF hospitalisation. Other outcomes of interest were QoL, thirst, NYHA class, N-terminal pro-Brain Natriuretic Peptide (NT-proBNP) and kidney function.

Data sources and selection process

A systematic search was conducted in the following databases without restrictions in publication date until 1 May 2025: Cumulative Index to Nursing and Allied Health Literature (CINAHL), Excerpta Medica dataBASE (EMBASE), PubMed and the Cochrane Library. The following search terms were used: "Heart Failure", "Stroke Volume", "Ventricular Dysfunction" and "Fluid Therapy". The search strategy for each database is found in online supplemental tables S1-4. Additionally, the reference list of included studies and relevant reviews were screened for eligible studies.

Two researchers (JJH and RvB) independently screened and selected studies for potential inclusion using EndNote V.21 (Clarivate, Philadelphia, Pennsylvania).

Data extraction and risk of bias assessment

Data from each included study were independently extracted into a prespecified data extraction table by the same two researchers responsible for the study selection process in Excel (Microsoft Corporation, Redmond, Washington). The extracted data included general study information, details on patient inclusion criteria, type of intervention and control, baseline information about the total population, duration of follow-up and primary and secondary outcomes. Risk of bias was assessed by the same two researchers independently using the Cochrane risk of bias V.2.0 tool.[16] All discrepancies between the two researchers were resolved by discussion and in case of no consensus, the opinion of a third investigator (FG) was decisive.

RESULTS

The search results are shown in figure 1. First, 1906 studies were identified, and four records were added through citation searching. Following the screening and removal of duplicates, a total of four RCTs comprising 682 patients, with a range of 46 to 504 participants per study, were included in this review.[17–20] One RCT by Reilly *et al* met the inclusion criteria but was only available as a conference abstract. It is probable that the study has not been subjected to peer review and was therefore not included in this review.[21] Study characteristics are summarised in table 1.

The trials were conducted in both Europe (Ireland,[20] Sweden[19] and the Netherlands)[18] and the USA.[17]

The majority of the studies were parallel RCTs,[17 18 20] and the study by Holst *et al* had a crossover design.[19] Albert *et al* included recently discharged patients,[17] Herrmann *et al* only stable outpatient patients[18] and Holst *et al* a combination of these groups.[19]

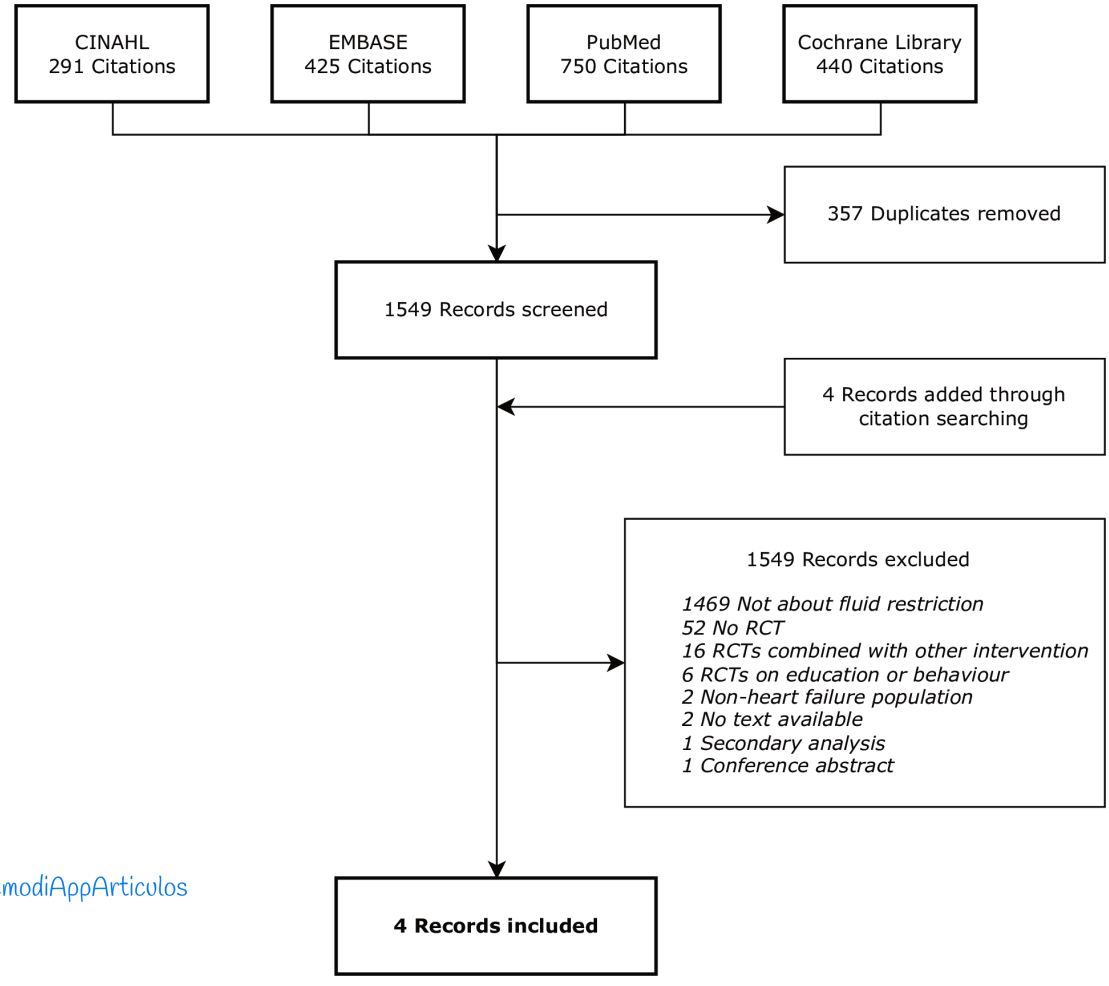

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Figure 1 Study flow diagram. CINAHL, Cumulative Index to Nursing and Allied Health Literature; EMBASE, Excerpta Medica dataBASE; RCT, randomised controlled trial.

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Table 1 Characteristics of the included studies

Study	Design	Country	Patient population	Setting	Heart failure type	Sample size	Intervention	Intervention, N	Duration of intervention	Comparator	Comparator, N	Follow-up
Albert *et al*, SALT-HF, 2013[17]	Single-centre, single-blinded, parallel pilot RCT	The United States of America	Patients at hospital discharge for acute decompensation of CHF with hypervolemic/euvolemic hyponatremia≤137 mg/dL	Outpatient after discharge	All	46	1000 mL/day+usual care discharge instructions and education	20	60 days	Usual care discharge instructions and education	26	60 days
Herrmann *et al*, FRESH-UP, 2025[18]	Multicentre, open-label, parallel RCT	The Netherlands	CHF with NYHA class II/III without recent (<3 months) HF hospitalisation, coronary intervention or pacemaker device implantation, or recent (<14 days) changes in medical HF therapy	Outpatient	All	504	1500 mL/day	250	3 months	Liberal fluid intake	254	6 months
Holst *et al*, 2008[19]	Multicentre, single-blinded, cross-over RCT	Sweden	At hospital discharge or outpatient CHF who have been improved from NYHA class (III) IV to a stable condition	Outpatient	EF≤45%	65	1500 mL/day	65	32 weeks	30–35 mL/kg/day	65	32 weeks
Travers *et al*, 2007[20]	Single-centre, single-blinded, parallel RCT	Ireland	Patients admitted for class IV HF	Inpatient	All	67	1000 mL/day	34	Until clinical stability	Liberal fluid intake	33	Until clinical stability

CHF, chronic heart failure; FRESH-UP, Fluid Restriction in Heart Failure versus Liberal Uptake study; HF, heart failure; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; RCT, randomised controlled trial; SALT-HF, Strict Allowance of Fluid Therapy in Hyponatremic Heart Failure study.

The inpatient population was investigated by Travers *et al*.[20] Studies were either single blind[17 19 20] or open label.[18] The upper limits of the fluid restriction were 1000 mL[17 20] or 1500 mL[18 19] per day and comparators were liberal fluid intake,[18 20] less strict fluid restriction[19] or usual care.[17] Follow-up time had a maximum of 32 weeks (figure 2).

Risk of bias assessment

The risk of bias assessment is summarised in table 2.

The study by Herrmann *et al* was assessed as low risk of bias in each domain.[18] The remaining studies were assessed as having a high risk of bias[19] or at least some concerns.[17 20]

Outcomes

The summary of findings is displayed in table 3.

All-cause mortality

Mortality was reported by three of the included studies,[17–19] all in the outpatient setting.

Albert *et al*[17] reported one death in the restriction arm and four in the usual care group. Herrmann *et al*[18] reported two deaths and one death in the restriction and liberal intake arms, respectively, during the 6-month follow-up. Holst *et al*[19] detailed on four deaths occurred during the restriction period (three sudden deaths and one due to deterioration of chronic HF) and two deaths (myocardial infarction and deteriorating of chronic HF) occurred during the more unrestricted (30–35 mL/kg/day) intervention.

None of these findings was found to be significantly different between the study arms but all the trials reported inadequate statistical power.

HF hospitalisations

The same three studies[17–19] reported on HF hospitalisations, with no significant differences between the randomised groups. Albert *et al*[17] showed no differences in occurrence or trends in (time to first) HF hospitalisation. Herrmann *et al*[18] reported only four patients who were admitted for HF in each randomisation arm. Holst *et al*[19] reported 12 readmissions, evenly distributed across both intervention periods. One third of these were attributable to a single patient. Once more, the statistical power is inadequate for drawing any conclusions.

Quality of life

QoL was assessed by using the Kansas City Cardiomyopathy Questionnaire (KCCQ),[17 18] Minnesota Living with Heart Failure Questionnaire[19] and European Quality of Life Five Dimensions Five Levels questionnaire (EQ-5D-5L).[18 19]

With regard to KCCQ, the two available RCTs showed contradictory results.[17 18] In the study by Albert *et al*, with 46 patients enrolled at the time of hospital discharge, KCCQ follow-up scores increased in both randomisation arms, and KCCQ follow-up scores were significantly higher and increased more in restricted patients.[17] Despite numerical differences in baseline scores, no correction for baseline values was performed. Herrmann *et al* with 504 patients with enrolment at the outpatient clinic showed higher scores at follow-up in the liberal intake group after correction for baseline values (significant higher scores for KCCQ Clinical Summary Score, Total Symptom Score and Symptom Frequency Score; non-significant higher score for KCCQ-OSS; p=0.06).[18]

For MLWHF, no differences between groups were observed by Holst *et al*.[19] Also for EQ-5D-5L, no differences were observed in this study as well as in the study by Herrmann *et al*.[18]

Thirst distress

Thirst distress was higher in restricted patients as assessed by the Thirst Distress Scale for patients with HF in the study by Herrmann *et al*[18] and Visual Analogue Scale (VAS) in the study by Holst *et al*.[19] The latter study also described a carry-over effect on thirst with regard to the order of the restricted and liberal intake period.[19] Albert *et al* showed no differences in thirst distress as measured by VAS.[17]

NYHA class and laboratory tests

Holst *et al*[19] found no differences in NYHA class between intervention groups. Finally, both (NT-pro)BNP and creatinine

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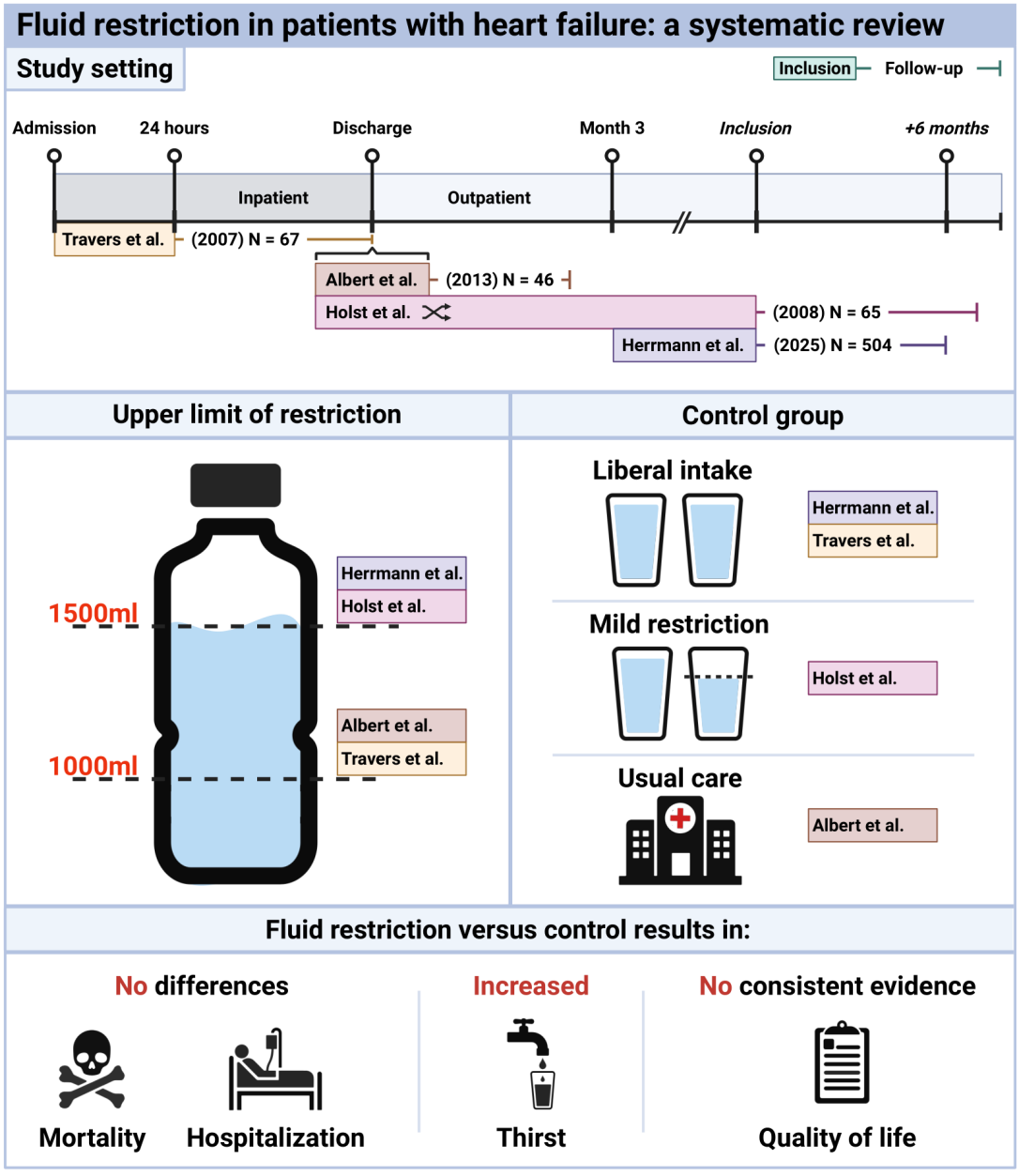

Figure 2 Visual take-home graphic.

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Table 2 Risk of bias summary

	Randomisation process	Bias arising from period and carryover effects	Deviations from intended interventions	Missing outcome data	Measurement of the outcome	Selection of the reported result	Overall bias
Albert *et al*, SALT-HF, 2013[17]	?	NA	+	?	+	?	?
Herrmann *et al*, FRESH-UP, 2025[18]	+	NA	+	+	+	+	+
Holst *et al*, 2008[19]	+	−	−	−	+	+	−
Travers *et al*, 2007[20]	+	NA	+	?	+	?	?

+ Low risk.
? Some concerns.
− High risk.
FRESH-UP, Fluid Restriction in Heart Failure versus Liberal Uptake study; SALT-HF, Strict Allowance of Fluid Therapy in Hyponatremic Heart Failure study.

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concentrations showed no significant between-group differences in any of the studies investigating this outcome.[18–20]

DISCUSSION

This systematic review, which included four RCTs comprising 682 patients with HF, assessed the most recent evidence on the effects of fluid restriction. Studies on fluid restriction in patients with HF remain scarce and most of the available studies are at high risk of bias. In the available studies, no evidence was found that fluid restriction affects mortality or HF hospitalisations. Second, in all but one study, fluid restriction did not improve QoL, while fluid restriction appeared to increase thirst distress.

This systematic review focuses on the sole effects of fluid intake in patients with HF without other cointerventions. Previous systematic reviews have included trials that also intervened with different sodium diets or diuretic doses simultaneously with the fluid restriction, which may mask the true effect of just fluid restriction.[11 22–26] Moreover, the recent publication of the Fluid Restriction in Heart Failure versus Liberal Uptake (FRESH-UP) study by Herrmann *et al* with 504 patients with HF adds substantial evidence on this topic, which was not included in the previous reviews.[18 27]

In this current systematic review, it was shown that concerns remain about the quality of the data on fluid restriction in HF. The sample sizes of the four included RCTs are relatively small, while the study by Herrmann *et al* accounts for almost three quarters of the total patient population. In terms of bias, selection bias is likely due to the small number of included patients per study and the fact that most studies were performed in the outpatient setting, which limits generalisability. Moreover, the studies were highly heterogeneous in terms of not only patient population (ie, acute vs chronic HF) but also study design (ie, parallel or cross-over), intervention (ie, fluid restriction ranging from 1000 to 1500 mL/day), follow-up time (ie, ranging from 'until clinical stability' up to 32 weeks) and outcome assessment (eg, a variety of questionnaires was used). Regarding outcomes, in most of the studies, patients were excluded from the analyses in case of non-compliance or drop-out, while no correction was made for missing data.[17 19 20] These shortcomings of the available data should be acknowledged, but there are lessons to be learnt from this systematic review.

For mortality and HF hospitalisations, the results were quite consistent as none of the studies showed a significant difference during follow-up and such events in all studies combined

Table 3 Summary of main findings

Study	Follow-up	All-cause mortality	HF Hospitalisation	All-cause hospitalisation	Quality of life	Thirst	NYHA class	(NT-pro)BNP	Creatinine
Albert *et al*, SALT-HF, 2013[17]	60 days	Restriction: 1 Usual care: 4	Relative incident rate 0,84 (95% CI 0.34 to 1.93; p=0.68) in favour of restriction.	NR	KCCQ (-OSS, -CSS, -TSS and -SBS) follow-up scores and increases were significantly greater in the restriction group than in the usual care group. (OSS: 72.6 ((52.2–86.3)) vs 51.0((37.7–68.5); P=0.038. CSS: 75.5 ((57.8–92.9)) vs 59.1 ((35.7–77.3); P=0.039. TSS: 77.1 ((58.1–91.7)) vs 54.2 ((30.2–73.9); P=0.022. SBS: 83.3 ((68.8–91.7)) vs 50 ((29.2–79.2); P=0.018). No correction for baseline scores.	No differences based on visual analogue scale (0–100) (Restriction: 40 ((20.0–51.3)) vs usual care: 50 ((12.5–73.8); P=0.60).	NR	NR	NR
Herrmann *et al*, FRESH-UP, 2025[18]	6 months	Restriction: 2 Liberal intake: 1	Restriction: 4 Liberal intake: 4	Restriction: 15 Liberal intake: 20	KCCQ-OSS follow-up score was higher in liberal intake group (unadjusted 72.2 (69.9–74.7) vs 74.0 (71.5–76.6); P=0.056). CSS, TSS and SFS were significantly higher in liberal intake patients (CSS: unadjusted 74.5 (71.9–77.1); vs 75.9 (73.4–78.4); P=0.032. TSS: 77.2 (74.5–79.9) vs 78.5 (73.4–78.4); P=0.020. SFS: 77.6 (74.8–80.3) vs 79.3 (76.6–81.9); P=0.014). EQ-5D-5L showed no differences (Restriction: unadjusted 0.83 ((0.72–0.92)) vs liberal intake: 0.81 ((0.70–0.89); P=0.45). Correction for baseline values was applied.	More thirst distress in the restriction group based on TDS-HF (8-40) (mean 18.6 (17.5–19.6) vs 16.9 (15.8–18.0); p<0.001).	NR	No differences after 3 months (Restriction: NT-proBNP 527.2 ng/L([196.4–1411.5)) vs liberal intake: 422.0((173.0–1200.0); P=0.19) and 6 months (Restriction: 553.8 ((179.8–1425.0)) vs liberal intake: 530.5 ((185.8–1300.5); P=0.65).	NR
Holst *et al*, 2008[19]	32 weeks	Restricted period: 4 (1 CHF/3 sudden death). Less strict period: 2 (1 CHF/1 myocardial infarction).	Restricted period: 6 Less strict period: 6	NR	MLWHFQ improved during both cross-over intervention periods. Improvement was significant only during the first period. No differences in MLWHFQ (Restriction: 20 (11-40) vs less strict: 17 (9-44); P=0.95) and EQ-5D-5L (Restriction: 0.80 ((0.66–0.92)) vs less strict: 0.80 ((0.70–0.92); P=0.75) at the end of both periods.	More thirst distress during the restricted period based on visual analogue scale (0–100) (51 (16-69) vs 23 (6-53); <0.001).	No differences.	NR	No differences (Restricted: mean 127±55 vs less strict: 130±54; P=0.30).
Travers *et al*, 2007[20]	Until clinical stability	NR	NR	NR	NR	NR	NR	No differences (Restriction: mean BNP 602.0 ng/L±644.8 vs liberal intake: 560.9±439.2; P=0.94.	No differences (Restriction: 128.2 umol/L±37.5 vs liberal intake: 111.7±30.5; P=0.06).

Values are mean (95% CI) or median (IQR), unless otherwise specified.
CHF, chronic heart failure; -CSS, Clinical Summary Score; EQ-5D-5L, European Quality of Life Five Dimensions Five Levels questionnaire; FRESH-UP, Fluid Restriction in Heart Failure versus Liberal Uptake study; HF, heart failure; KCCQ, Kansas City Cardiomyopathy Questionnaire; MLWHFQ, Minnesota Living with Heart Failure Questionnaire; NR, not reported; (NT-pro)BNP, (N-terminal pro-)B-type natriuretic peptide; NT-proBNP, N-terminal pro-Brain Natriuretic Peptide; NYHA, New York Heart Association; -OSS, Overall Summary Score; SALT-HF, Strict Allowance of Fluid Therapy in Hyponatremic Heart Failure study; -SBS, Symptom Burden Score; -SFS, Symptom Frequency Score; TDS-HF, Thirst Distress Scale for patients with HF; -TSS, Total Symptom Score.

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were exactly the same in the two groups. Nevertheless, due to the limited sample sizes, it is inappropriate to draw definitive conclusions.

For QoL, the results are somewhat contradictory, but overall, there is no clear benefit of fluid restriction on QoL. In the two studies by Herrmann *et al* and Holst *et al*, including a total of 569 patients, no effect or a small increase in QoL by liberal fluid intake was shown.[18 19] The other study by Albert *et al* (comprising 46 patients) suggested an increase in QoL by fluid restriction. The observed potential positive effect of fluid restriction was of concern of bias as not all included patients were analysed and only 18 (75%) and 23 (82%) patients completed the follow-up QoL questionnaires in the restriction and usual care groups, respectively.[17] Moreover, in this particular trial, a fluid restriction of 1 L/day was studied, which may be more bothersome for the general HF population in daily clinical practice. With regard to thirst distress, one study was neutral, and two demonstrated an increase in thirst sensation as a result of fluid restriction.[17–19]

Previously published systematic reviews (in combination with meta-analyses) that included trials in which fluid management, sodium intake and/or diuretics were intervened simultaneously, were mostly inconclusive or negative regarding the benefits of fluid restriction in HF.[11 22–25] None of these reviews comprised all the trials included in this systematic review. The only review concluding that fluid restriction may be beneficial was primarily based on trials combining multiple interventions.[22]

In summary, at present, there is no clear evidence of a beneficial effect of fluid restriction in patients with HF. There is, however, a signal of harm of fluid restriction in terms of thirst distress and potentially also QoL. Taken together, the current evidence does not support the widespread and routine use of fluid restriction in patients with HF. Further research into fluid restriction in HF is needed to provide more clarity for daily clinical practice and may especially focus on the patients with acute and advanced HF with limited renal function.

Some limitations of this review should be noted. Although two researchers (one of whom was not involved with the FRESH-UP study) independently carried out the screening process, data extraction and risk of bias assessment, relevant trials may have been missed. A meta-analysis was not considered appropriate because of the high heterogeneity of the included studies. Finally, because sodium restriction is frequently a part of the non-pharmacological treatment of patients with HF, potential effects of concomitant sodium restriction cannot be completely excluded despite the careful selection of the included studies.

Conclusion

Studies on fluid restriction in patients with HF are scarce. Sample sizes are small and studies lack statistical power. Most of the available studies lack high quality. As none of the studies showed a significant effect on mortality or HF hospitalisations during follow-up, there is no clear evidence of benefit of fluid restriction in patients with HF. There is a signal of harm of fluid restriction in terms of thirst distress and potentially QoL. Taken together, the current evidence does not support the routine use of fluid restriction in patients with HF.

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